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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,709	10/18/2001	Albrecht Sippel	WEICKM-13	7039

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	6

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,709	SIPPEL ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, the products of claims 1-34, 60, and 63, drawn to cell comprising a membrane receptor, and the methods of claims 35-37, 39-45, and 47 drawn to an in vivo assay for determining the suitability of a test substance as a ligand for the receptor by contacting the cells with the substance wherein the receptor may activate a signal pathway when a ligand binds the receptor.

Group II, the products of claims 1-34, 60, and 63, drawn to cell comprising a membrane receptor, and the methods of claims 38 and 46 drawn to an in vivo assay for determining the suitability of a test substance as a ligand for the receptor by contacting the cells with the substance wherein the receptor may activate a signal pathway when there is a lack of ligand binding.

Group III, claims 48-50, drawn to in vivo assays for quantitative determination of the concentration of a ligand for a receptor.

Group IV, claims 51-54drawn to in vivo assays to determine whether a compound is able to alter the binding activity of a receptor with relation to a ligand.

Group V, claims 55-58, drawn to in vivo assays for detecting if a polypeptide or protein has a ligand binding function of a receptor by determining if the test substance activates a cell receptor, and claims 63-65, drawn to kit intended for use in the claimed method.

Group VI, claim 59, drawn to an in vivo assay for detecting if a polypeptide or protein has a ligand binding function of a receptor by determining if the test substance inactivates a cell receptor.

Group VII, claims 61, 62, and 66-69, drawn to a kit comprising cell in which the Ras or a Ras-like signal pathway cannot be activated in at least certain conditions, and nucleic acid vectors that encode a membrane receptor and other polypeptides or proteins.

Group VIII, claim 70, drawn to a method of identifying proteins or polypeptides with the ligand binding function of a receptor

For each of Groups I and II above, restriction to one of the following is also required. Therefore, election is required of one of Groups I-VIII, and, if one of Groups I or II is elected, to one of inventions (A1)- (A6), one of the inventions of (B1)- (B4), one of the inventions of (C1)- (C2), and one of inventions (D1)-(D4).

Subgroups (A1)- (A6) represent the cells of the elected invention wherein the effector protein or polypeptide is a fusion protein that comprises an effector section:

(A1) that is a guanine nucleotide exchange factor;
(A2) that is an active protein from the Ras family;
(A3) that is a GRK2 kinase;
(A4) that is a GRK3 kinase;
(A5) that is a Src homology 2 domain; or
(A6) that is a pleckstrin homology domain:

Subgroups (B1)- (B4) represent the cells of the elected invention wherein the effector protein or polypeptide is a fusion protein that comprises an adaptor protein that is:

(B1) able to interact with the β and γ subunits of a G-protein after the alpha subunit is dissociated there from;
(B2) able to interact with the alpha subunit of a G-protein after it has been dissociated from the other subunits thereof;
(B3) the protein Gbr2; or
(B4) the protein Shc.

Subgroups (C1)- (C2) represent the cells of the elected invention wherein (C1) the membrane receptor is one of the receptors of (C-i) to (C-v), or (C2) the ligand binding sections of the synthetic membrane receptor is derived from one of the receptors of (C-i) to (C-vii).

In addition to electing one of the receptors of C1 or C2, the applicant must also elect under 35 U.S.C. 121 one of the following inventions. If the applicant elected Group C1 above, the applicant must also elect one of groups C-i to C-v. If the applicant instead elected group C2 above, the applicant must then also elect one of Groups C-i to C-vii.

Groups C-i to C-vii represent the elected cell wherein the membrane receptor is or comprises a ligand binding section derived from:

(C-i) a transmembrane receptor, (C-ii) an enzyme-coupled receptor,
(C-iii) a G-protein-coupled receptor, (C-iv) a 7-transmembrane receptor,
(C-v) an odor (or olfactorial) receptor, (C-vi) a nuclear receptor, or
(C-vii) a synthetic ligand binding section generated by molecular modeling.

Subgroups (D1)-(D4) represent the cells of the elected invention wherein the mediator section:

(D1) comprises the cytoplasmic part of a G-protein-coupled receptor that activates a PI3K;
(D2) is in put into a position in appropriate circumstances of exerting a tyrosine kinase activity;
(D3) is in put into a position in appropriate circumstances of exerting a serine/threonine kinase activity; or
(D4) is in put into a position in appropriate circumstances of exerting a phosphatase activity.

For each of Groups I, III, IV, V above, restriction to one of the following is also required. Therefore, election is required of one of Groups I-VIII, and, if one of Groups I, III, IV, or V is elected, to one of inventions (E1)-(E2).

Subgroups E1 and E2 represent the assays of the elected Group, wherein the method comprises:

(E1) detecting the expression of a reporter gene in the presence of the test substance: or
(E2) detection of the ability of cells to reproduce in the presence of the test substance.

2. The inventions listed as Groups E1 and E2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of these methods has a different mode of operation in making the same determination not used by the other. As the two methods operate in a different manner, they do not share a common special technical feature.

3. The inventions represented by groups A1-A6, B1-B4, C1 and C2, Ci-Cvii, and D1-D4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of the members of the different subgroups have different structures and functions from the other members.

4. . The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of these groups describes cells that perform different functions in that they have different reactions to ligands to the membrane receptors of the cell.

5. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 with the inventions of Groups III-VI and VIII because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: under these rules, the applicant is entitled to examination of only a single method with an elected product. As the other Groups identify methods other than the first of using the claimed products, the applicant is not entitled to examination of these other methods.

6. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 with Group VII because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The kits of Group VII and the cells of Groups I and II share only the technical feature of a cell in which the Ras or Ras-like signal pathway cannot be activated in certain conditions. This is not a feature that distinguishes over the prior art. Also, the kits have addition features on which to rely for patentability (the vectors) that are not included in the cell. Thus, the inventions do not share a special technical feature that distinguishes both inventions from the prior art.

Species Election

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group A1 above comprises two claimed species of the elected invention. If this group is elected the applicant must also elect one of species A1(a) (wherein the GEF effector section is the CD25 protein from Sacchromyces cerevisiae), or species A1(b) (wherein the GEF effector domain is an SOS protein). Claim 2 is generic to these species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

8. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined . If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

9. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

10. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
January 6, 2003

JAMES HOUSEL 1/13/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600